Journal of Orthodontics, Vol. 33, 2006, 38–44

SCIENTIFIC SECTION

An Investigation into the Use of a Single Component Self-etching Primer Adhesive System for Orthodontic Bonding: a randomized controlled clinical trial

K. House and A. J. Ireland
Department of Child Dental Health, Bristol Dental Hospital, Bristol, UK

M. Sherriff
Department of Dental Biomaterials Science, Guy's Hospital, London, UK

Objective: This study assessed the *in vivo* bond failure of the single component orthodontic self-etching primer system, Ideal 1 (GAC Orthodontic Products) and compared it with the conventional acid etching using a conventional 37% *o*-phosphoric acid, rinsing and drying regimen when bonding stainless steel orthodontic brackets to enamel.

Design: Prospective randomized, controlled clinical trial.

Setting: Orthodontic Department, Bristol Dental School.

Material and methods: Twenty consecutive patients undergoing upper and lower fixed orthodontic treatment entered this cross-mouth control study. Diagonally opposite quadrants were randomly allocated to either the self-etching primer group or the conventional etching group. A total of 339 teeth were bonded with Ideal 1 light-cured adhesive. Bond failures and locus of bond failure were then recorded at 1, 6 and 12 months.

Results: Significantly more bond failures occurred at each of the 3 time intervals, 1, 6 and 12 months, where the enamel was pretreated with the Ideal I self-etching primer, than when the enamel was treated with the conventional etchant, 37% *o*-phosphoric acid. With the latter the cumulative bond failure rates were 3.0, 5.3 and 14.8%, respectively. With the self-etching primer the cumulative failure rates were 29.4, 56.5 and 72.4%.

Conclusion: The study found that enamel pre-treatment with the Ideal 1 self-etching primer system prior to orthodontic bonding results in an unacceptably high bond failure rate when compared with conventional enamel acid etching.

Key words: Bonding, composite, self-etching primer

Received 9th February 2005; accepted 22nd November 2005

Introduction

In order to bond orthodontic brackets to enamel and achieve an optimal bond, it is generally acknowledged that the enamel should be etched for 15–30 seconds with 37% *o*-phosphoric acid, followed by rinsing with copious amounts of water and air dried until frosty white in appearance.[1–3] This process consists of a number of time-consuming steps, namely etching, rinsing, priming, and then adhesive and bracket placement, and in recent years there has been a move to try to simplify this process. The introduction of self-etching primers for orthodontic use has been seen as a means of doing just this, creating a reliable enamel bond whilst streamlining the bonding process. Self-etching primers contain a methacrylated phosphoric acid ester active component that etches and primes simultaneously. Unlike conventional acid etch methods, the self-etch primer is not rinsed away after application; the calcium dissolved from the hydroxyapatite forms a complex with the phosphate group and this is then incorporated into the resin network when the primer is polymerized. The obvious potential advantages of such primers include improved patient comfort, as there is no need to rinse, a reduction in chairside time and, therefore, improved cost-effectiveness. However, to be considered truly

Address for correspondence: Dr A. J. Ireland, Department of Child Dental Health, Bristol Dental Hospital, Lower Maudlin Street, Bristol BS1 2LY, UK.
Email: tony.ireland@tiscali.co.uk

DOI 10.1179/146531205225021375

cost-effective not only must these self-etching primers reduce the number of procedural steps and be easy to use, but they must also produce a reliable clinical bond for the duration of treatment and then leave the enamel unblemished at the end of treatment when the appliance is removed.

Many researchers have conducted *in vitro* studies to investigate bond strengths of self-etching primers. Initially, products that were designed for restorative use were tested for possible orthodontic use. However, even between similarly designed studies and sometimes involving the same authors, there appeared to be no consensus view concerning the observed shear bond strength and, therefore, usefulness in orthodontic bonding.[4–7] In addition, following concerns about enamel fractures at debond, the manufacturers of the restorative self-etching primer Prompt-L-Pop (3M ESPE) advised against using this product for orthodontic bonding. This product was subsequently modified for orthodontic bonding and is marketed as Transbond Plus™ self-etching primer (3M/Unitek, Dental Products Division, Monrovia, CA, USA). This self-etching primer, like most of the self-etching primers on sale, is a 2-component system that requires mixing prior to use. *In vitro* experiments using this and other self-etching primers have yielded encouraging results, suggesting that their bond strength is comparable if not higher than that observed following the use of a conventional 37% orthophosphoric acid etch.[8–11]

Although there are many laboratory studies indicating that brackets can be successfully bonded with self-etching primers, there are few published clinical studies. Prospective clinical trials by Asgari *et al.*[12] and Ireland *et al.*[13] evaluated the bond failure rates using Transbond Plus™ self-etching primer over a 6-month period. Asgari *et al.*[12] concluded that bracket retention using this self-etching primer was superior to that seen following traditional acid etching, whereas Ireland *et al.*[13] reported a bond failure rate of 10.9% following use of the self etching primer, compared with a failure rate of only 4.95% for the control of conventional acid etching.

In an attempt to further simplify the bonding process a 1-component no-mix self-etching primer has been developed where no pre-mixing is required prior to its use. This single component self-etching primer is marketed as part of a complete kit of etchant and adhesive by GAC International, and is known as the Ideal 1 adhesive system (GAC International Inc., Bohemia, NY, USA). The Ideal 1 adhesive within the kit is a conventional filled diacrylate composite resin. To date, no *in vivo* investigations have been published assessing the clinical performance of this single component self-etching primer system. However, an *in vitro* study comparing the shear bond strength of the Ideal 1 system with a 2-component self-etching primer system found that both systems produced similar bond strengths.[14] The results of a further *in vitro* study[15] performed by the authors of the present *in vivo* investigation also observed that the force to debond following the use of the Ideal 1 self-etching primer was comparable with that of the conventional etch and rinse control. However, as always, caution should be exercised when extrapolating the results of *in vitro* studies to the clinical situation.

Therefore, the aim of this study was to investigate the *in vivo* bond failure rates of the single component orthodontic self-etching primer system, Ideal 1 (GAC Orthodontic Products) and to compare it with the conventional acid etching, rinsing and drying regimen. In both cases, the brackets used were stainless steel orthodontic brackets and the adhesive was Ideal 1 filled diacrylate adhesive (GAC Orthodontic Products).

The following null hypotheses were tested:

1. There is no significant difference in the in service bond failure rates between the Ideal 1 self-etching primer system and that based on conventional acid etching.
2. Treatment time has no significant effect on observed bond failure rates of the 2 enamel preparation methods under test.
3. There is no significant difference in the locus of bond failure between the 2 enamel preparation methods tested.

Material and methods

Thirty consecutive patients attending the Orthodontic Department, Bristol Dental School, UK, and receiving upper and lower fixed appliances, were to be enrolled in the study for a period of 1 year to fit in with the operator's orthodontic training schedule. A power calculation had determined that 30 patients (15 non-extraction patients with 20 orthodontic brackets each and 15 four premolar extraction cases with 16 orthodontic brackets each) would be required to give a power of 0.9 at a significance level of 0.05, assuming failure proportions of 5% and 13%, which was deemed a clinically significant difference.[13,16,17] A split mouth study design was used and the power calculation was base on truly independent samples (i.e. individual teeth rather than patients). A limitation of the design however is that the individual teeth are not truly independent, as they will all be linked together by the archwire and

failure of 1 bracket may influence the likelihood of failure of adjacent brackets. However, a cross-mouth study allows for a self-control model. Subjects were eligible for inclusion in the study if they satisfied the following selection criteria: patients receiving only metal brackets on upper and lower arches, bands to be placed on molar teeth only, no restorations that would preclude bonding to enamel. Local research ethics committee approval was sought and obtained prior to commencing recruitment of patients into the study (Central and South Bristol Local Research Ethics Committee, Project number E5506). All subjects who were eligible for inclusion were provided with information leaflets describing the purpose of the trial and were given the opportunity to ask the researcher questions. Interested patients gave their written consent to their participation in the study. Fortunately, 100% of the patients eligible for inclusion agreed to participate.

Patients were treated by 1 operator (KH) at the University of Bristol Dental School and acted as their own controls, the split mouth technique being used. The bonding protocol for each patient followed a contralateral pattern to eliminate operator bias. One quadrant was randomly selected to receive the self-etching primer and adhesive system (Ideal 1—GAC International), together with the contralateral quadrant in the opposing arch. The teeth in the other 2 quadrants were treated with 37% orthophosphoric acid etchant and brackets bonded with the same Ideal 1 adhesive. Patients were not informed as to which were the experimental and control quadrants, and randomization was achieved by using random numbers from a random number table and a system of sealed envelopes.

All teeth in both the experimental and control quadrants were pumiced for 5–10 seconds per tooth with pumice in water slurry, using a rubber cup and a slow speed hand piece. The teeth were then rinsed with water, dried with oil-free compressed air and isolated with retractors. Each quadrant was bonded and cured individually, beginning with the experimental quadrants. In these quadrants the operator applied the self-etching primer to the surface of each tooth by rubbing the primer gently on the enamel surface using the microbrush supplied, and for 20 seconds per tooth in accordance with the manufacturer's instructions. A gentle blast of air was then applied to each tooth in that quadrant, for 5 seconds per tooth in an occlusal direction to thin the material. Ideal 1 adhesive was then applied to the bracket base (Omni 0.022-inch meshed based stainless steel brackets, GAC International Inc., Bohemia, NY, USA), the bracket was placed firmly on the tooth using a Mitchell's trimmer and the excess adhesive removed from around the periphery using a probe. The adhesive was then light cured, from posterior to the anterior, for 20 seconds per tooth (10 seconds per interspace) using a halogen-curing lamp (Ortholux, 3M Unitek). The lamp was checked prior to use on each patient using the inbuilt light meter.

The control quadrants were etched with 37% orthophosphoric acid for 15 seconds each, rinsed with copious amounts of water and the enamel was then air dried until frosty white in appearance. Once again, Ideal 1 adhesive was applied to the bracket base (Omni 0.022-inch, GAC International Inc., Bohemia, NY, USA), the bracket placed firmly on the tooth, and the excess removed and light curing was performed as for the experimental quadrants. However, in order to ensure the previously bonded brackets were not exposed to further light during curing of the control quadrants, a sheet of rubber dam was placed carefully over the previously bonded brackets in the adjacent and opposing quadrants. Once the brackets had been bonded to the teeth, elastomeric separators were placed at the first molar teeth.

One week after bond placement and separation the patients returned for band and archwire placement. 0.010-inch 'stainless steel lacebacks were placed in all 4 quadrants and 0.012-inch superelastic nickel titanium archwires were then placed and tied-in with elastomeric modules. At subsequent appointments, the archwire sequence for all patients was 0.016-inch superelastic nickel titanium followed by the archwires that were deemed to be appropriate for each individual case. The lacebacks remained in place and were gently retightened to remove any slack at each visit, although they were still passive.

Any brackets that did fail during treatment were rebonded, but using conventional acid etching of the enamel and these teeth were subsequently excluded from the trial. In addition, brackets that were electively debonded for repositioning during treatment to improve bond position were also excluded from the study and any subsequent data analysis. Any adhesive remaining on the enamel surface at bond failure was assessed and scored according to the Adhesive Remnant Index (ARI) as follows:[18]

Score 0: no adhesive left on the tooth.
Score 1: less than half of the adhesive left on the tooth.
Score 2: more than half of the adhesive left on the tooth.
Score 3: all the adhesive left on the tooth, with a distinct impression of the bracket mesh.

Data on bond failure were collected at 1 and 6 months and 1 year after placement.

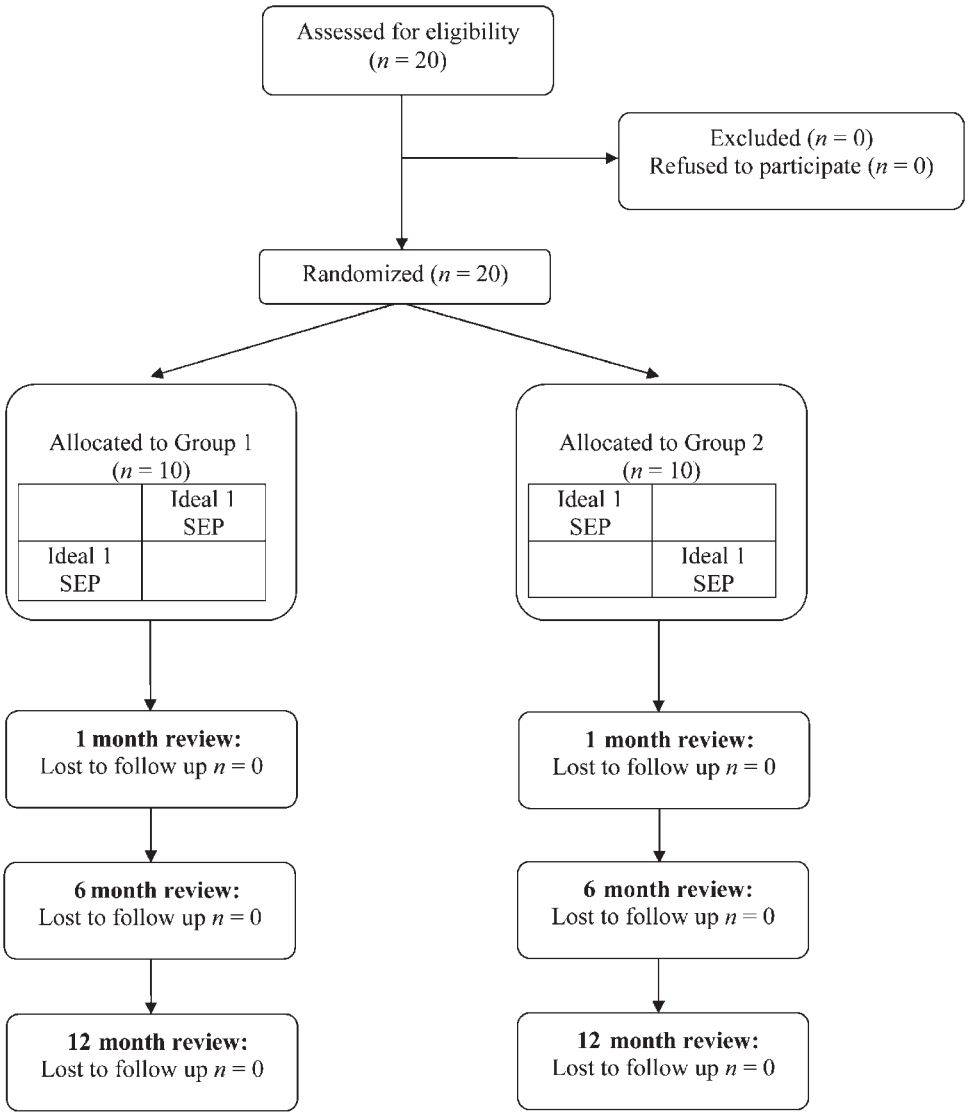

Figure 1 CONSORT flow diagram showing progress of subjects through trial

Results

No patients were lost to follow-up during this trial. However, due to the large number of bond failures noticed early on in the study, patient recruitment was stopped prematurely and in total only 20 patients, rather than the planned 30 patients were recruited into the study. A CONSORT diagram showing the flow of patients through each stage of the trial is shown as Figure 1. Previous work has shown bond failure rates of up to 19.5%[19] may be observed with new orthodontists in training. When it was apparent that the bond failure rate in the experimental group at 6 months was 56.5%, a decision was made to cease further recruitment. It would have been unethical to continue the trial when it was evident that the Ideal self-etching primer being trialled had such a high failure rate.

Data was analysed using Stata 9.1 (Stata Corp. College Station, Texas, USA) with a predetermined significance of α=0.05. The distribution of failure as a function of treatment, namely Ideal 1 self-etching primer/Ideal 1 adhesive or conventional etching/Ideal 1 adhesive, with time is shown in Table 1. It can be seen that at the 1, 6 and 12 month time periods the cumulative bond failure rates in the control, conventional etch, group were 3.0, 5.3 and 14.8%, whilst in the self-etching primer group the values were 29.4, 56.5 and 72.4%, respectively. There was therefore a clinically significant difference between the 2 groups and over all three time periods.

The data was analysed in terms of the odds ratio (OR) and 95% confidence intervals of self-etching primer specimens failing relative to the conventional acid etch control (Table 2). An OR of 1 would signify no difference between the groups. At each of the three time periods, the OR is much greater than 1, indicating a significant difference between the failure rates of the 2 treatment groups. The test of homogeneity indicated that there was no significant difference between the OR for the three time periods, the differences being attributed to chance. As a consequence it is possible to calculate a common OR using the Mantel–Haenszel method.[20] This common OR is also high, again indicating a significant difference between the 2 main treatment groups of self-etching primer and conventional acid etch control.

A Kruskal–Wallis one-way analysis of variance was performed to determine the effect of enamel pre-treatment, namely self-etching primer versus conventional etching, on the Adhesive Remnant Index (ARI) scores of the brackets that failed during treatment. Unfortunately, at the time of rebond, the operator did not record the ARI scores of 9 brackets from the experimental group and one from the control group. From the observed and recorded data the Kruskal–Wallis one-way analysis of variance appears to demonstrate a significant difference in the ARI scores between the 2 treatment groups (self-etching primer $n=114$, conventional etch $n=24$, $p=0.03$). This difference is illustrated in Figure 2, where it can be seen that, in both groups, the principal mode of failure was at the enamel surface (score 0), although in the conventional etch group there was also a more mixed mode failure, with ARI scores of both 2 and 3.

Discussion

From the results of this study, it is apparent that the use of the single component self-etching primer under test leads to unacceptably high bond failure rates of up to 72.4%. This compares with a maximum of 14.8% over the whole 12 month study period for conventional acid etching. There was no significant effect of time. There were some observed differences in the locus of bond failure, with there being more adhesive remaining on the enamel surface following the use of conventional etching than with the self-etching primer.

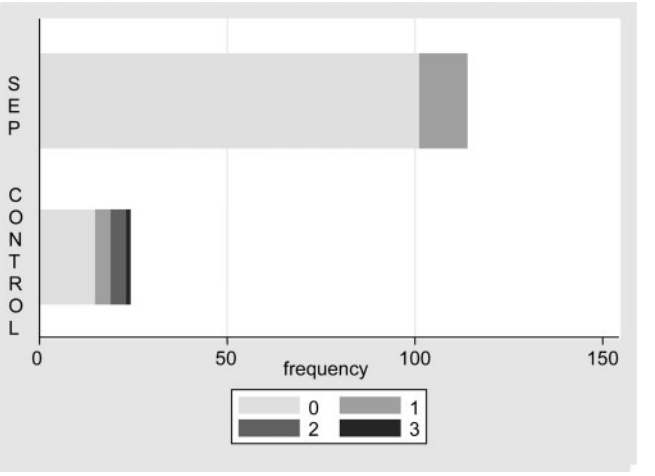

Figure 2 ARI scores for the Ideal 1 self-etching primer and Ideal 1 adhesive group (SEP), and the conventional etch and Ideal 1 adhesive groups (control)

Although a cross-mouth controlled trial has limitations with respect to independence of the samples, i.e. individual teeth, this model does have the advantage of providing a self-control. The effect of the treatments in this case were largely confined to each of the defined quadrants of the mouth. In addition, the numbers of variables were carefully controlled in an attempt to compare only the enamel pre-treatments, Ideal 1 self-etching primer and the conventional acid etch regimen. This includes the use of only 1 operator. Previously

Table 2 Odds ratio (OR) and 95% confidence interval of failure of self-etching primer relative to conventional etch, and the Mantel-Haenszel combined OR

Time	OR	95% CI
1 month	13.7	4.9 to 37.8
6 months	23.1	9.5 to 55.9
12 months	15.1	7.7 to 29.3
Common OR	16.9	10.6 to 27.1

Test of homogeneity of OR: $\chi^2=0.76$, p=0.68

Table 1 Distribution of failure as a function of treatment and time

	Initial bonds	Cumulative number of bonds failing		
Treatment		1 month	6 months	12 months
Self-etching primer	170	50 (29.4%)	96 (56.5%)	123 (72.4%)
Conventional etch	169	5 (3.0%)	9 (5.3%)	25 (14.8%)

reported trials involving different self-etching primers have used multiple operators increasing the chance of experimental bias. Although the operator was at the very beginning of her postgraduate training in orthodontics, the observed bond failure rates were actually lower for the conventional acid etch group, when compared with the previous reports of bond failure rates of up to 19.5% for operators at the equivalent stage of training.[19]

A large number of *in vitro* studies investigating the bond strengths of self-etching primers have produced encouraging results that are comparable with those seen following conventional etching.[4–9] However, few studies have investigated the clinical efficiency of self-etching primers for orthodontic bonding and none to date have investigated the use of a single component self-etching primer in the clinical situation. This study was designed to assess the clinical performance of such a product over a 12 month period. However, the results were surprising and very disappointing, given the encouraging results displayed by previous *in vitro* studies using the same self-etching primer.[14,15] In retrospect, it would also be appropriate in future studies to define in advance what failure rate is unacceptable so that clear criteria exist that specify when recruitment should be terminated (rapidly if necessary).

Analysis of the ARI scores using the Kruskal–Wallis one-way analysis of variance (Figure 2) showed that the locus of bond failure was significantly different ($p=0.03$) between the control conventional etch group and the experimental Ideal 1 self-etching primer group. However, in both groups the mode of failure was principally adhesive at the enamel/resin interface, although more resin remained on the enamel surface in the conventional acid etch group. This tendency for the locus of bond failure to predominate at the enamel adhesive interface when using self-etching primers is in agreement with laboratory studies into their use.[4,6,10,21,22] However, locus of bond failure has not previously been reported in a clinical trial of self-etching primers.

The results of this randomized clinical trial necessitate that the null hypotheses of no difference between the 2 enamel pre-treatment regimens should be rejected. The reason for the poor clinical performance of this single component self-etching primer in comparison with other clinical trials where Transbond Plus^{TM} SEP was tested is unclear. However, the locus of bond failure being predominately at the enamel-adhesive interface may be indicative of a less than optimal enamel adhesive bond.

When deciding on which bonding system to use, ease of application and reduction in application time can only confer a true advantage if a reliable bond to enamel is also achieved. With a cumulative bond failure rate over 12 months as high as 72.4%, the Ideal 1 self-etching primer obviously does not meet the latter requirement. Much of the current work on self-etching primers has been *in vitro* in nature and, although laboratory tests are an important stepping stone in the development of a product, they can never truly replicate the oral environment and, as such, act as a definitive test of clinical effectiveness. The conflicting results of this clinical trial and the previously conducted *in vitro* studies,[14,15] using the same materials, are an example of this problem.

Therefore, despite previously encouraging laboratory findings, based on the results of this clinical trial the authors cannot recommend Ideal 1 self-etching primer system for clinical use, due to the unacceptably high level of in-service bond failures.

Conclusions

The results of this *in vivo*, randomized, cross-mouth clinical trial suggest that enamel pre-treatment with the Ideal 1 self-etching primer system results in an unacceptably high bond failure rate when compared with conventional enamel acid etching and, as such, it cannot be recommended for clinical use.

Authors and contributors

Dr K. House was responsible for recruitment of participants, obtaining patient consent and data collection; analysis; drafting, critical revision, and final approval of the article. Dr M. Sherriff was responsible for data interpretation and statistical analysis. Dr A. J. Ireland was responsible for study design; obtaining ethical approval; logistic, administrative, and technical support and data interpretation; critical revision and final approval of the article.

Dr A. J. Ireland is the guarantor and, as such, accepts full responsibility for the conduct of the study, has access to the data and controlled the decision to publish.

Acknowledgements

The authors wish to thank TOC, for supplying the Ideal 1 system and Omni Brackets used in this study.

References

1. Kinch AP, Taylor H, Warltier R, Oliver RG, Newcombe RG. A clinical trial comparing the failure rates of directly

bonded brackets using etch times of 15 or 60 seconds. *Am J Orthod Dentofacial Orthop* 1988; **94**: 476–83.
2. Wang WN, Lu TC. Bond strengths with various etching times on young permanent teeth. *Am J Orthod Dentofacial Orthop* 1991; **100**: 72–9.
3. Gange P. Present state of bonding. *J Clin Orthod* 1995; **7**: 429–36.
4. Bishara SE, Gordon VV, VonWald L, Olson ME. Effect of an acidic primer on shear bond strength of orthodontic brackets. *Am J Orthod Dentofacial Orthop* 1998; **114**: 243–7.
5. Bishara SE, Ajlouni R, Laffoon JF, Warren JJ. Effect of a fluoride-releasing self etch acidic primer on the shear bond strength of orthodontic brackets. *Angle Orthod* 2002; **72**: 199–202.
6. Korbmacher H, Klocke A, Huck L, Kahl-Nieke B. Enamel conditioning for orthodontic bonding with a single-step bonding agent. *J Orofac Orthop* 2002; **63**: 463–71.
7. Aljubouri YD, Millett DT, Gilmour WH. Laboratory evaluation of a self etching primer for orthodontic bonding. *Eur J Orthod* 2003; **25**: 411–15.
8. Arnold RW, Combe EC, Warford JH. Bonding of stainless steel brackets to enamel with a new self-etching primer. *Am J Orthod Dentofacial Orthop* 2002; **122**: 274–6.
9. Buyukilmaz T, Usumez S, Karaman AI. Effect of self-etching primers on bond strength—are they reliable? *Angle Orthod* 2003; **73**: 64–70.
10. Larmour CJ, Stirrups DR. An *ex vivo* assessment of a bonding technique using a self-etching primer. *J Orthod* 2003; **30**: 225–8.
11. Dorminey JC, Dunn WJ, Taloumis LJ. Shear bond strength of orthodontic brackets bonded with a modified 1-step etchant-and-primer technique. *Am J Orthod Dentofacial Orthop* 2003; **124**: 410–13.
12. Asgari S, Salas A, English J, Powers J. Clinical evaluation of bond failure rates with a new self-etching primer. *J Clin Orthod* 2002; **36**: 687–9.
13. Ireland AJ, Knight H, Sherriff M. An *in vivo* investigation into bond failure rates with a new self-etching primer system. *Am J Orthod Dentofacial Orthop* 2003; **124**: 323–6.
14. Bishara SE, Oonsombat C, Ajlouni R, Laffoon JF. Comparison of the SBS of 2 self-etch primer/adhesive systems. *Am J Orthod Dentofacial Orthop* 2004; **125**: 348 – 50.
15. House K. An investigation into the effectiveness of a single component self-etching primer system for orthodontic bonding. DDS dissertation, University of Bristol, 2005.
16. Altman DG. *Practical Statistics for Medical Research*. London: Chapman & Hall, 1991.
17. UCLA Department of Statistics: http://calculators.stat.ucla.edu/powercalc/
18. Årtun J, Bergland S. Clinical trials with crystal growth conditioning as an alternative to acid-etch enamel pre-treatment. *Am J Orthod* 1984; **85**: 333–40.
19. Ireland AJ, Sherriff M. The effect of timing of archwire placement on *in vivo* bond failure. *Br J Orthod* 1997; **24**, 243–5.
20. Agresti, A. *An Introduction to Categorical Data Analysis*. Hoboken NJ: Wiley Interscience, 1996.
21. Yamada R, Hayakawa T, Kasai K. Effect of using self-etching primer for bonding orthodontic brackets. *Angle Orthod* 2002; **72**: 558–64.
22. Cacciafesta V, Sfondrini MF, De Angelis M, Scribante A, Klersy C. Effect of water and saliva contamination on shear bond strength of brackets bonded with conventional, hydrophilic, and self-etching primers. *Am J Orthod Dentofacial Orthop* 2003; **123**: 633–40.